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MINISTRY OF FOOD

FOOD STANDARDS COMMITTEE
REPORT ON
COLOURING MATTERS

Recommendations relating to the use of colouring matters in foods

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FOOD STANDARDS COMMITTEE

The Food Standards Committee was appointed by the Minister of Food in 1947 with the following terms of reference:

To advise the Ministers of Food and Health and the Secretary of State for Scotland as to the provision to be made concerning the composition of foods (other than liquid milk) and the labelling or marking of any foods for which such provision is made, by:

(*a*) Statutory Orders under the Defence (Sale of Food) Regulations; or

(*b*) Regulations (other than Milk and Dairies Regulations) under the Food and Drugs Acts, and corresponding enactments relating to Scotland;

for preventing danger to health, loss of nutritional value or otherwise protecting purchasers.

The members of the Food Standards Committee are:

Norman C. Wright, Esq., M.A., D.Sc., Ph.D., F.R.I.C. (*Chairman*).
G. G. Barnes, Esq., C.B.E. (*Vice-Chairman*).
C. A. Adams, Esq., C.B.E., B.Sc., F.R.I.C., Barrister at Law.
N. R. Beattie, Esq., M.D., D.P.H.
Professor S. J. Cowell, M.B., F.R.C.P.
A. Glover, Esq., M.Sc., F.R.I.C.
A. J. Howard, Esq., M.A., F.R.I.C.
J. M. Johnston, Esq., M.D., F.R.C.S.(Edin.), F.R.S.E.
G. W. Monier-Williams, Esq., O.B.E., M.C., M.A., Ph.D., F.R.I.C.
J. R. Nicholls, Esq., C.B.E., D.Sc., F.R.I.C.
R. W. Sutton, Esq., B.Sc., F.R.I.C., F.C.S.
G. Taylor, Esq., O.B.E., F.R.I.C.
R. F. Tyas, Esq.
Miss E. Walker, O.B.E.
R. Wright, Esq., B.Sc., A.R.C.S.

Joint Secretaries:

W. M. Shortt, Esq., M.Sc., F.R.I.C.
Mrs. J. J. Tait.

PRESERVATIVES SUB-COMMITTEE

The Preservatives Sub-Committee was appointed by the Food Standards Committee in January, 1951, with the following terms of reference:

To review the Public Health (Preservatives etc., in Food) Regulations and to make any recommendations the Sub-Committee may consider desirable for the amendment of the Regulations.

The members of the Preservatives Sub-Committee are:

Sir Charles Dodds, M.V.O., M.D., D.Sc., F.R.C.P., F.R.I.C., F.R.S. (*Chairman*).
C. A. Adams, Esq., C.B.E., B.Sc., F.R.I.C., Barrister at Law.
Professor S. J. Cowell, M.B., F.R.C.P.
A. Glover, Esq., M.Sc., F.R.I.C.
E. B. Hughes, Esq., D.Sc., F.R.I.C.
J. M. Johnston, Esq., M.D., F.R.C.S.(Edin.), F.R.S.E.
H. E. Magee, Esq., M.B., D.Sc., M.R.C.P.
J. R. Nicholls, Esq., C.B.E., D.Sc., F.R.I.C.
G. Roche Lynch, Esq., O.B.E., M.B., B.S.(Lond.), D.P.H., F.C.G.I., L.M.S.S.A., F.R.I.C.
R. F. Tyas, Esq.

Joint Secretaries:

W. A. Godby, Esq., M.B.E., F.R.I.C.
B. W. Smith, Esq.

FOOD STANDARDS COMMITTEE REPORT ON COLOURING MATTERS

The Food Standards Committee have considered and adopted a Report by their Preservatives Sub-Committee recommending that the Public Health (Preservatives etc. in Food) Regulations should be amended so as to permit the use in foods of specified colours only. The Report is in the following terms:—

I. Introduction

1. We were appointed as a Sub-Committee of the Food Standards Committee in January, 1951, with the following terms of reference:—

> " To review the Public Health (Preservatives etc. in Food) Regulations and to make any recommendations which the Sub-Committee may consider desirable for the amendment of the Regulations."

2. Because of the wide range of substances to be covered by our investigations we decided to report on each class of substances separately. Antioxidants have already been reported on and this Report on Colouring matters is the second in the series.

II. General Observations

3. The practice of colouring food is very old. References are made by Pliny the elder to the colouring of wine; the colouring of spices and condiments was practised some 500 years ago. Colours were probably first introduced into foods to mask a deficiency of ingredients such as eggs, butter, chocolate and fruit, or to improve the appearance of some product the original colour of which had deteriorated during manufacture. Their main purpose to-day is to give a more attractive appearance to foods.

4. Until the middle of the 19th century the only colouring matters available were derived from natural sources and comprised mineral pigments and colours of animal or vegetable origin. In the latter half of that century the so-called " coal-tar " colours, discovered about 1850, began to be used in foods. The " coal-tar " dyes provided a much wider range of colours of high tinctorial power and of greater brilliance than those hitherto used. Their use rapidly gained favour with food manufacturers and at the present time they have largely replaced the natural colours.

5. Soon after the introduction of " coal-tar " colours as food additives the question was raised whether from the toxicological standpoint they were suitable for use in foods. A number of countries controlled their use by legislation. In some the use in foods of synthetic colours, other than those specifically named, was prohibited; in others colours considered unsuitable for use in foods were banned.

6. A Departmental Committee was appointed by the Minister of Health in 1923 to inquire into the use of preservatives and colouring matters in foods and to report:—

- (i) whether the use of such materials, or any of them, for the preservation and colouring of food is injurious to health, and if so, in what quantities does their use become injurious; and
- (ii) whether it should be required that the presence of such materials and the quantities present in food offered or exposed for sale should be declared.

7. In its Report, issued in 1924, the Committee recognised that general permission to use any colour (with certain specified exceptions) might be convenient to the trade. It was pointed out that this would allow the use of a very large number of dyes about which there was not adequate information of their physiological action. Accordingly the Committee felt that the proper course was to consider each colouring matter individually and to approve its use only if the evidence demonstrated its harmless character.

8. The Committee recommended:—

(i) that the employment of a copper salt to colour or preserve the colour of peas and other vegetables (a practice then common) should be prohibited; and

(ii) that a list of colouring matters the use of which may be considered non-injurious to health should be drawn up, and that only such colours should be permitted in foods.

9. The adoption of the second recommendation would have necessitated a detailed examination of the biological properties of each of the synthetic colours then in use. The Government of the day, however, decided on a different approach, and under the Public Health (Preservatives etc. in Food) Regulations, 1925, the use in food of certain colours then known to be harmful was prohibited. These were:—

(i) Compounds of any of the following metals:—

Antimony
Arsenic
Cadmium
Chromium
Copper
Lead
Mercury
Zinc

(ii) The vegetable colouring matter—Gamboge.

(iii) The following five " coal-tar " colours:—

Picric Acid
Victoria Yellow
Aurine
Manchester Yellow
Aurantia

10. Section 9 (i) (*a*) of the Food and Drugs (Milk, Dairies and Artificial Cream) Act, 1950 prohibits the addition of colouring matter to milk.

11. The present position in this country, therefore, is that any colours not specifically prohibited by the Public Health (Preservatives etc. in Food) Regulations, 1925 to 1953 may be used in foods (other than milk) provided such use does not contravene the provisions of sections 1 and 3 of the Food and Drugs Act, 1938.

12. Most other countries, including the United States and Canada, have adopted the alternative course of allowing only specified colours to be used in foods or to be present in imported foods. In some countries the purity of the permitted colours is controlled by strict specification, and in the United States each batch of colour must be officially certified as suitable for food use before sale. The lists of permitted colours are subject to amendment in the light of scientific evidence bearing on the suitability of any particular colour for use in foods.

13. Since 1925 evidence has been accumulating which indicates that there are " coal-tar " colours in addition to the five at present prohibited in this country, which may present a health hazard if used in food, and others having a similarity in chemical structure are now regarded with suspicion.

14. It is obvious that in the interests of public health only colours which will not have any deleterious effects when consumed over long periods should be used in foods. Whether this can best be achieved by extending the present list of prohibited colours or by the introduction of a list of permitted colours is the main issue.

III. The Sub-Committee's Review

15. The following aspects appeared to us to merit detailed examination:—

(i) whether the addition of colour to foods is necessary or desirable;
(ii) whether the addition of colour to any particular food or class of foods should be prohibited;
(iii) what information in respect of the pharmacological action of colours is available;
(iv) whether the present system of control by means of a list of prohibited colours should be continued or should be replaced by a list of permitted colours;
(v) what colours should be prohibited or permitted;
(vi) whether specifications of purity should be prescribed for food colours;
(vii) whether the amount of colour used in foods should be limited;
(viii) whether the purchaser should be notified by label declaration or other means of the addition of colour to foods;
(ix) whether the sale of food colours should be controlled;
(x) whether legal provision should be made to control the importation of foods containing added colour.

(i) *Is the addition of colour to food necessary or desirable?*

16. In our review of the Preservatives Regulations we have worked on the assumption that it is not in the public interest for a chemical substance to be added to food unless there is a demonstrable advantage in its addition, and that there is adequate scientific evidence that its use in food will not affect adversely the health of the consumer.

17. We realize that colour could be used to mask the use of inferior ingredients or to give a false impression of quality. On the other hand it is generally accepted to be physiologically sound that food should be presented in as attractive a form as possible, and without the addition of colour many foods would have a drab unattractive appearance.

18. If, therefore, there is adequate evidence that the colours used have no deleterious effects on health we see no objection to their use to replace natural colour lost during processing, to standardise appearance or simply to render a product more attractive.

(ii) *Should the addition of colouring to particular foods or classes of foods be prohibited?*

19. Paragraph 180 of the report of the Departmental Committee stated:—

> " We have considered that it is not within the terms of our reference to enquire into and report upon the question as to what substances should be allowed to be coloured artificially, although it is evident that colour is frequently used to cover up objectionable or inferior materials, or to give a factitious appearance, so that the articles so coloured masquerade for something which they are not."

Our terms of reference are, however, sufficiently wide for this to be considered.

20. There is no sharp dividing line between the use of colour to mask inferior ingredients or to give a false impression of quality and for the purposes indicated in paragraph 18. Again public opinion may change with the passing of time, and while the first introduction of colour into foods may well have been designed to give a false impression of quality the colouring of food has become so generally accepted that it is unlikely that the purchaser to-day is misled. Although the dyeing of smoked fish, particularly kippers, has now become an established practice, we regard this as an instance where the use of colour could have been challenged originally. We are aware that where the use of colour is such that the food could be challenged in the Courts as being not of the nature, substance or quality demanded and the purchaser is thereby prejudiced, proceedings could be instituted under section 3 of the Food and Drugs Act, 1938.

21. There is some controversy as to whether colour should be permitted to be added to jams and marmalades made from fresh fruit. In the Food Standards (Preserves) Order, 1944 (S.R. & O. 842) it was provided that " Fresh Fruit Standard Jam " and " Fresh Fruit Standard Marmalade " should not contain added colouring matter, but when the Order was revised in 1953, no provision for "Fresh Fruit Standard Jam" was made. Some fresh fruits, such as strawberries, on conversion into jam lose much of their natural bright colour and the appearance of the product can be improved by the addition of a little colour. We see no objection to this practice.

22. To the best of our knowledge in this country colour is not added to natural foods such as milk and meat, game, poultry, fish, fruit and vegetables sold in the raw state. The addition of colour to milk is already prohibited, and we are of the opinion that a similar prohibition should apply to all these foods.

(iii) *Pharmacological aspects of colouring matters*

23. In November, 1951, publicity was given to our review, and information was invited as to the substances used in foods, the purposes of the addition, the amounts added, and where available their biological action.

24. The information received on colouring matters has been carefully examined by a Pharmacology Panel of the medical members of the Sub-Committee. A survey of information on " coal-tar " colours is given in Appendix I and the findings of the Pharmacology Panel are contained in Appendix II.

25. On the evidence available the Panel placed the " coal-tar " colours reviewed in the following categories:—

Class A—colours which appeared to be innocuous when consumed in the amounts customarily used for colouring foods;

Class B—colours for which evidence was scanty or conflicting, but for which there was at present no reason to suggest that they were potentially harmful in the amounts ordinarily consumed in foods;

Class C—colours which have been shown to have, or are suspected to have, harmful effects on health.

26. The Sub-Committee endorse the classifications recommended by the Pharmacology Panel and agree that any proposed list of permitted colours for use in food should be compiled from those classified as A or B, the latter being included only to the extent that the class A colours are insufficient to meet reasonable trade requirements.

27. Still more comprehensive tests are desirable to extend and confirm the scientific evidence already presented on which the safety of food colours, even after long usage can be assessed. In particular it is most important that generally acceptable methods of biological tests for colours should be specified, which should cover such factors as species and number of animals under test, dosage and duration of the experiments. The criteria for assessing the suitability of food colours on the basis of these tests should also be indicated.

(iv) *Should the present system of a prohibited list be continued or be replaced by a permitted list of colours?*

28. In a memorandum proposing the revision of the Public Health (Preservatives etc. in Food) Regulations, submitted to the Ministers of Food and Health in March, 1950, by a Joint Committee appointed by the Society of Public Analysts and other Analytical Chemists—now the Society for Analytical Chemistry—and the Society of Chemical Industry (Food Group) it was recommended inter alia that:—

> " A list of the only colours permitted to be used in foods should be given, such a list to be subject to frequent revision. As a basis the colours now in common use should be considered, and the whole matter should be investigated carefully in conjunction with the manufacturers of food colours."

29. We have given detailed consideration to the arguments advanced in support of the retention of the present system of a list of prohibited colours and those for the introduction of a list of permitted colours, and have taken into account the views submitted by the various interests concerned.

30. The salient points in favour of a list of permitted colours are:—

(i) the introduction of a list of permitted colours adjudged to be suitable for use in food would afford greater protection both to the consumer and food manufacturer, since merely to prohibit use of colours known to be harmful would still leave in use a very large number for which there is little or no biological information;

(ii) further biological research would be required in respect of comparatively few colours;

(iii) most other countries who have already studied this problem have adopted the principle of a list of permitted colours;

(iv) provision could readily be made for the revision of a list of permitted colours.

31. On the other hand the main points submitted to us in support of a list of prohibited colours were:—

(i) a list of prohibited colours has been in operation in the United Kingdom since 1925, and food mnaufacturers have received no complaints of illness due to the consumption of foods containing added colour.

(ii) A large variety of colours is required in the U.K. food industry; colours of the same shade are not necessarily suitable for every class of food. The present system gives the necessary freedom of choice to the food manufacturer; and enables foods manufactured for export, which conform to the laws of the importing country in respect of " coal-tar " colours, to be sold on the home market.

(iii) Although certain " coal-tar " colours have been shown to have adverse effects on the health of experimental animals it does not follow that human beings would be similarly affected.

(iv) The present list of prohibited colours could be extended to include any colour proved to be harmful.

For the reasons given below we have felt unable to accept these contentions.

32. Control must be designed to safeguard public health as effectively as possible. In our opinion the present list of prohibited colours does not meet this requirement. Prudence suggests that ideally only colours for which there is adequate experimental evidence of harmlessness should be permitted to be used in foods.

33. During the last twenty years evidence has been accumulating which indicates that certain "coal-tar" colours, not at present prohibited, are carcinogenic to experimental animals and doubts have been expressed regarding others. The number of "coal-tar" colours is very large and new colours are constantly being introduced. The majority are not manufactured with a view to their use in food, although there is no clear legal restriction on such use. It is not surprising, therefore, that there is little or no information of the pharmacological action of the great majority of "coal-tar" colours. Even for the colours commonly employed in foods there is seldom sufficiently comprehensive information for a conclusive opinion to be formed whether or not any health hazard might arise when they are consumed in foods over long periods.

34. For effective control a list of prohibited colours would need to include all "coal-tar" colours known to be harmful, those which are regarded with suspicion, and those which have not been submitted to pharmacological investigation, and would need to be constantly revised as new colours were introduced. This would be a cumbrous procedure and the same measure of control could be achieved much more readily by specifying the colours which may be used in foods.

35. We consider that the introduction of a list of permitted colours for use in food, restricted to those which the available evidence indicates are harmless, is in the best interests of public health. Much can be said in favour of endeavouring to include colours permitted in other countries, especially in the United States and Canada, but the fact that a colour is permitted to be used in another country does not in our opinion justify its adoption for use in the U.K., if its harmlessness is open to question.

(v) *What colours should be permitted in foods?*

36. The Departmental Committee (1924) found it convenient to divide colouring matters used in foods into three groups, viz.:—

Mineral Pigments—such as Armenian bole and other oxides of iron.

Natural organic colours—which include colours of vegetable or animal origin such as annatto, saffron, cochineal, etc., the lakes of these colours, and caramel.

Synthetic organic colours—chiefly of "coal-tar" origin.

37. The Departmental Committee were unaware of any evidence that the few natural organic colours and pigments then used in food were harmful; but since instances had occurred of the employment, through ignorance, of poisonous inorganic colouring substances they thought that harmless natural organic colours and pigments should be included in a list of approved colours and should conform to specified standards of purity.

38. In Germany the only natural colours permitted appear to be carotene, chlorophyll and cochineal; in Peru cochineal and vegetable colours which contain no toxic alkaloids or glucosides are permitted. In France and Uruguay synthetic indigotin, alizarin and their sulphonic acid derivatives are classified as vegetable colours, and their use in foods allowed. In India, we understand, it is proposed to permit only vegetable colours and pigments which occur naturally in edible fruits or vegetables.

39. No question arises as to the suitability for use in foods of any colour which is a normal constituent of edible products. This generalisation does not, however, apply to all colours derived from natural sources. Indeed, the chemical structure and biological action of many of the colouring matters extracted from the root, bark, fruit, leaves, blossoms, or stems of plants are unknown.

40. Our consideration of natural colouring matters has been confined to the following substances stated to be those at present used for colouring food, namely:—

> Armenian bole and other oxides of iron, carbon black, annatto, flavine, orchil, cochineal, alkannin, persian berry extract, saffron, turmeric chlorophyll, carotene and caramel.

Provided that these substances can consistently be produced to the requisite degree of purity we see no objection to their use or to the use of any of these colours which can be prepared synthetically.

41. " Coal-tar " colours are usually regarded with more suspicion than natural colours. The assessment of the suitability of colours for use in food can only be based on existing knowledge which may be modified in the light of further research. We understand that the colours on the United States list are at present being re-examined.

42. The Federal law of the United States probably imposes greater control of food colours than the law of any other country. Colours permitted to be used in food, drug and cosmetics are referred to as F.D. & C. colours and every batch of such colour must be certified by Government analysis before use. The original United States list of permitted colours of 1907 comprised 7 " coal-tar " colours which had been selected after a review of the evidence then available on their physiological effects. The current list contains 19 colours which have been widely accepted as suitable for use in food. All the colours on the United States list have been approved officially by Canada.

43. At one time we had in mind to recommend adoption of the United States (F.D. & C.) list but since it had been represented that this list would be insufficient to meet the present needs of the food industry in this country, we had no option but to review all colours (totalling 79) submitted to us as at present being used for colouring food.

44. Each of these colours was critically examined by the Pharmacology Panel, and as a result a preliminary list consisting of 28 colours was circulated to food manufacturing interests as a basis for further discussion.

45. The substance of the representations received from the various sections of the food industry on the Sub-Committee's preliminary proposals for a permitted list of food colours is given below:—

(i) *Confectionery and Miscellaneous Manufactured Foods*—It was emphasised that a large number of colours was necessary to provide the variety in appearance of confectionery to which the consumer had become accustomed. It was not economic to manufacture special lines of confectionery for export, and in view of the importance of maintaining export trade particularly to the United States and Canada, it was urged that use of all the colours permitted in these countries should be allowed. If it were decided to introduce a permitted list of food colours, there would be great advantage in having a common list for the U.K., the United States and Canada; there should be arrangements for the addition to the list of colours of proved harmlessness. Difficulties were anticipated if manufacture of colours not on the permitted list were discontinued in the U.K.

(ii) *Bakery Products*—The Sub-Committee's proposals made inadequate provision for oil-soluble colours, and the absence of many of the F.D. & C. colours and of a black colour might create difficulties. It was suggested that use of Sudan Red G, an oil-soluble colour, and of Baking Brown AW, which was very useful in the bakery industry, should be permitted.

(iii) *Dairy Products*—Annatto was the only substance used for colouring butter and cheese and, subject to the need for providing a distinctive colouring for the rind of some cheeses, no objection was seen to the prohibition of the use of " coal-tar " colours in these dairy products. It was stated that synthetic dyes might be found in imported processed cheese.

(iv) *Margarine*—Carotene was used for colouring 75–80 per cent. of the total U.K. production of margarine but some manufacturers used " coal-tar " colours. Annatto was not suitable for colouring margarine. Only two colours (Oil Orange XX and Oil Yellow GG) on the preliminary list were suitable for colouring margarine, and these would have to be blended to give the desired shade. These two colours were not generally available in this country and doubts were expressed as to the stability of Oil Yellow GG in the presence of alkali. It was considered desirable that any permitted list introduced should be co-ordinated with the lists of other countries.

(v) *Soft Drinks, Essences and Flavourings, etc.*—There was a considerable export trade in flavouring and colouring compounds and it was particularly important that a permitted list should include as many as possible of the F.D. & C. colours. It was undesirable to limit any list to a fixed number of colours, and there should be facilities to have other harmless colours added to the list. It would also be of advantage if any list recommended were to apply throughout the Commonwealth. The use of the calcium and aluminium lakes of permitted colours should be allowed.

(vi) *Fish*—Any proposal to prohibit the colouring of fish would be resisted, and no reason was seen why the use of any harmless colour should not be permitted. The preliminary list of colours did not include Orange I, a colour at present employed on white fish.

(vii) *General*—It was represented that because of its better properties of fastness to sunlight and fruit acids Ponceau 3R was more suitable than Ponceau SX for use in certain foods packed in glass containers.

46. The above submissions were carefully reviewed and in particular the Pharmacology Panel re-examined the United States (F.D. & C.) colours, the oil-soluble colours, and the relevant biological information relating to these and other colours proposed. As a result, we have compiled the list given in Appendix III. We recognise that with the omission of Oil Orange XX (C.I. No. 73) this list may not include a synthetic colour or combination of colours suitable for colouring margarine. It seems to us that it would be contrary to the public interest to recommend use of other oil-soluble colours unless and until present doubts as to their pharmacological action have been removed. As regards margarine the use of carotene could be further extended.

47. While it has not been possible to meet in full the stated requirements of the trade, we have tried to provide as wide a variety of colours as possible consistent with the need for the protection of the public health, and recognise that provision ought to be made for additions to or deletions from the list of permitted colours should the need arise.

(vi) *Should specifications of purity be prescribed for food colours?*

48. The chemical purity of dyes used for colouring food is clearly of major importance. The purity of synthetic dyes may be adversely affected by the presence of impurities, such as arsenic, lead, intermediates and subsidiary dyes derived from the raw materials or resulting from the process of manufacture.

49. We understand that every endeavour is made to produce food colours of a high degree of purity, and that the production of such colours is kept separate from the manufacture of dyes for industrial purposes. Thus in the production of food colours only pure intermediates are used, and the reaction vessels are selected so as to eliminate or reduce metallic contamination to the lowest practical level.

50. The 1924 Departmental Committee came to the conclusion that colours intended for food purposes should not contain more than 1/100th grain per pound of arsenic (As_2O_3) and that the total amount of lead, copper, tin and zinc in aggregate should not exceed 20 p.p.m. In 1928 a Joint Committee of the then Society of Public Analysts and other Analytical Chemists and the Association of British Chemical Manufacturers investigated the arsenic content of food colours and recommended limits of 5 p.p.m. (As_2O_3) for pure colours; 3 p.p.m. for colours diluted with not more than twice their weight of diluent and 1·4 p.p.m. for colours diluted to a greater extent. The contamination of food colours with lead was investigated in 1935 by a Sub-Committee of the Analytical Methods Committee of the Society of Public Analysts and other Analytical Chemists. Most of the colours examined contained less than 20 p.p.m. of lead, although a few such as Armenian bole (ferric oxide) were found to contain up to 400 p.p.m.

51. The metallic contamination of foods has been under consideration by a Sub-Committee of the Food Standards Committee, appointed in 1948, who have recommended the following limits for arsenic, lead and copper, based in each case on the dry colouring matter:—

Arsenic—synthetic colours 1 p.p.m. (As)
other colouring matters 5 p.p.m. (As)

Lead—20 p.p.m.

Copper—30 p.p.m.

52. We regard it as essential that standards of composition and purity for each of the colours proposed for use in foods should be established before detailed biological investigations are undertaken.

53. The specification of appropriate limits for intermediates and subsidiary dyes requires further consultation with manufacturers, since each colour will need to be considered individually. In the case of the F.D. & C. colours included in Appendix III we see no reason why the specifications operative in the United States for these colours should not be adopted temporarily in this country.

(vii) *Should a limit be set to the amount of colour which may be used in foods?*

54. It is not the general practice for a statutory limit to be set for the amount of colour which may be added to foods. In Canada the amount of added colour must not exceed 1 part in 3,500 parts of the food (290 p.p.m.) and a similar limit is adopted in some of the Australian States. In Norway, there is a limit of 0·5g. per 10 Kg. of food (50 p.p.m.) while in Colombia the amount of "coal-tar" dye is limited to 100 p.p.m. In France, colour may only be employed in amounts strictly necessary for the colouring of food and drink to the customary extent. The Central Committee for Food Standards of India, 1952, have recommended a maximum limit of 1 grain per pound of food, which is about half that permitted in Canada.

55. We consider that no useful purpose would be served by prescribing maximum limits for the amount of colour which may be added to foods since the quantity will vary with the kind of food, the depth and tint of colour required and the tinctorial power of the dye.

(viii) *Should the purchaser be notified, by label declaration or other means, of the presence of added colouring?*

56. The Departmental Committee expressed the view that if colours of proven harmlessness only were permitted to be used in foods, it would be unnecessary, so far as health considerations were concerned, to require declaration of their presence, but did not deal with the question whether declaration of added colour should be required in order to prevent a purchaser from being misled as to the nature or quality of the article.

57. In the United States and Canada the words "colour added" must be placed conspicuously on the label of foods containing added colour.

58. During and since the last war fundamental changes have been made in the law relating to the labelling and advertising of foods in this country. Detailed labelling requirements have been prescribed in respect of prepacked foods. The Labelling of Food Order, 1953, requires, inter alia, the labels of compounded foods to bear a statement of each of the ingredients present. Certain foods are exempted from this requirement, notably intoxicating liquors, foods for which a standard has been prescribed, and foods for which labelling provisions exist in other enactments: the full list of exemptions is given in the First Schedule to the Order.

59. The provisions of the Labelling of Food Order apply only to prepacked foods and we have considered whether its provisions, so far as added colouring is concerned, should be extended to other foods. The Sub-Committee were not unanimous on this issue but the majority took the view that as a desirable general principle there should be a declaration of the presence in foods of added colour.

(ix) *Should control be exercised over the sale of food colours?*

60. Colours for use in food may be sold as the pure colour or mixture of colours; as a diluted colour containing non-colouring ingredients such as salt, sodium sulphate, sugar, alcohol, glycerin, etc.; or as a flavouring and colouring compound.

61. Food colours when prepacked for retail sale are at present required to conform with the provisions of Part II of the Labelling of Food Order, except that the "appropriate designation" of the colouring ingredients is not required; it being sufficient to declare the colouring contituents as "colour" if of natural origin, otherwise as either "synthetic" or "artificial colour".

62. If our recommendations are accepted that only the colouring matters specified in Appendix III should be permitted to be used in foods, and that specifications of purity should be prescribed for each colour, no legal control over the sale of such colours would seem to be necessary other than that afforded by adequate labelling. This in our view would be achieved if the provisions at present operative under the Labelling of Food Order for colours prepacked for retail sale were extended to cover all sales, and in addition the containers of colours intended for use in food were *conspicuously* marked with a description such as, Food Colour; Mixed Food Colour; or Food Colouring and Flavouring Compound.

63. The " appropriate designation " of the colour, as given in Appendix III, should be stated on the labels of single ingredient colours.

(x) *Are any special provisions necessary to deal with imported foods containing added colour?*

64. It is clear that any recommendations made should apply also to imported foods. It is appreciated that imported foods could not be held at the ports for the time necessary to enable Inspecting Officers to be satisfied that any added colour conformed to the U.K. Regulations. Assuming, however, that statutory effect is given to our recommendations, we presume the importer would demand a warranty that the food offered conformed to the regulations.

IV Summary of Conclusions

65. The colouring of foods, whether by natural or synthetic agents is a long established practice, to which we are not opposed provided the colouring agents employed have no adverse biological effects when consumed in foods over long periods.

66. We cannot accept the contention that, because " coal-tar " colours have been used in foods for many years without giving rise to complaint of illness, they are, therefore, harmless substances. Such negative evidence in our view merely illustrates that in the amounts customarily used in food the colours are not acutely toxic but gives no certain indication of any possible chronic effects. Any chronic effects would be insidious and it would be difficult if not impossible to attribute them with certainty to the consumption of food containing colouring matter.

67. We consider that the present Regulations under which in practice almost all known synthetic colours can be used in foods are unsatisfactory, and that the colours permitted to be used should ideally be restricted to those whose harmlessness has been established by adequate biological tests.

68. A review of scientific literature reveals that for only comparatively few colours is there information as to chronic toxicity or carcinogenicity. In the case of the majority of colours there is a lack of sufficiently comprehensive biological evidence to enable a conclusive opinion to be formed. Work is proceeding on the pharmacological examination of colouring matters but to the best of our knowledge few details have been published.

69. We do not accept the contention about frustrated exports as sufficient to justify the extension of the proposed list to include all the colours permitted in other countries. Nevertheless we fully appreciate the disadvantages inherent in the existence of different national lists, and we would support steps to facilitate exchange of biological information with a view to securing the greatest possible measure of uniformity.

70. We have confined our attention to the colours known to be used by U.K. food manufacturers and from an examination of the available data, the chemical structures and the possible course of metabolic breakdown have selected those colours which appear to us to be suitable for use in food. We would emphasise that at this stage the list of colours proposed is purely tentative, and we suggest that it should be reviewed when sufficient time has elapsed to enable further tests to be carried out. Our investigations point to the urgent need for authoritative guidance on the tests to which colouring matters should be submitted in order to establish that their use in foods would not present a health hazard.

71. Instances where use of colour in foods may be open to question have been discussed in paragraphs 19–22; and we have indicated those foods or classes of foods which in our opinion should not be permitted to be artificially coloured.

72. We consider it most important that specifications of purity should be prescribed for each of the permitted colours, and that discussions with the colour manufacturers should be entered into on this with the least possible delay.

73. It is the opinion of the majority of us that, where practicable, the purchaser should be informed by labelling or other means when a food contains added colour.

74. In so far as the sale of food colours is concerned we feel that the food manufacturer should be informed whether he is buying the pure colour or a diluted colour; and we have set out suggestions for the labelling of food colours in para. 62.

V. Recommendations

75. The following are our recommendations:—

(i) that the Public Health (Preservatives, etc., in Food) Regulations 1925–1953 should be amended so as to permit the use in foods of specified colours only;
(ii) that for the present, official approval should be given only to the colouring matters listed in Appendix III;
(iii) that the specified colours should be permitted to be used either singly or in any combination;
(iv) that specifications of purity should be prescribed and published for each of the specified colours;
(v) that the list of specified colours should be reviewed after a suitable period (say 5 years) in the light of any further evidence then available, subject to which and provided there is a demonstrable need colours may be added to or deleted from the list at any time;
(vi) that colours, other than for marking purposes, should not be permitted to be used in milk, or in or upon meat, game, poultry, fish, fruit, vegetables, sold in the raw or unprocessed state;
(vii) that in general notification of the presence in foods of added colour should be given to the purchaser. Exceptions to this general requirement may, however, prove necessary;
(viii) that colours sold for use in food should be appropriately labelled;
(ix) that any regulations which may be made as a result of these recommendations should apply also to imported foods.

F.S.C./P.V.T./REP 3.

29th November, 1954

APPENDIX I

Survey of "coal-tar" colours with special reference to the pharmacological aspect

1. The suitability for use in foods of "coal-tar" colours involves the question both of acute and chronic toxicity and of carcinogenicity. In this survey, which is based on a study of a wide range of literature, these two subjects are reviewed separately.

Acute and chronic toxicity

2. The permitted lists of food colours of different countries vary considerably both in the number and the nature of the colours approved. Of 22 lists, the number of "coal-tar" colours ranges from 7 (Portugal) to 38 (Australia). These lists cover 82 different colours, and only amaranth is common to all. The U.S.A. permitted list of 1907 contained 7 "coal-tar" dyes selected after a critical examination of all data published up to that time. Since then the U.S.A. list has been gradually extended until it now contains 19 colours.

3. The variation in permitted lists suggests much diversity of opinion about the advisability of using particular "coal-tar" dyes in foods, even although other considerations may have been taken into account. The conflicting opinions about a particular colour could not be ascribed solely to variations in chemical purity. The data upon which the 1907 U.S.A. list was based have been fully reviewed by Hesse (1912). Hesse's survey indicates that for the colours tested evidence of chemical purity was often lacking; and physiological data, often very incomplete, were available for only about 100 of the then known "coal-tar" colours. In view of the confusion and uncertainty, the U.S.A. authorities decided to consider for use in foods those colours for which only favourable reports had been made after biological examination. It was appreciated that the biological tests were not always sufficiently comprehensive to establish beyond doubt that a colour was innocuous and, therefore, not all dyes favourably reported on could be regarded as wholly satisfactory. It is not known for certain whether the extension of the list from 7 to 19 has been based upon published data or whether additional tests were carried out by the U.S.A. authorities.

4. Specifications of the chemical purity to which the F.D. & C. colours must conform have been published, but the standards adopted in assessing the pharmacological data are not available. Presumably any standard of assessment would depend on the state of biological knowledge at the time and would need to be revised in the light of advances in biological knowledge. This appears to be recognised by the U.S. Federal Food and Drugs Administration who, it is understood, are engaged in re-investigating the F.D. & C. colours. Reports have recently appeared on the metabolism of the F.D. & C. triphenylmethane dyes, Blue No. 1, Green No. 1, and Green No. 3 (Hess and Fitzhugh, 1953). The fact that a colour is included in the U.S.A. (F.D. & C.) list is widely accepted as a proof of its suitability for use in foods, but recent developments suggest that certain colours in that list are not above suspicion.

5. Sanction for the use in foods of any dye must depend, first of all, upon a specification of chemical purity. It is not enough to have a product free from arsenic and other mineral poisons. Information is needed about freedom from contamination from subsidiary dyes and especially from intermediates which may in themselves be more highly toxic than the actual dye.

6. No reliable information could be found regarding the metabolic fate in the human body of any of the chemical classes to which the dyes belong. Much fundamental research is necessary on such problems as the products of metabolic breakdown, sites of storage (if any), rate of elimination, and the effects of the presence and positioning in the molecule of substituent groups.

7. There is some evidence that the mono-azo dyes undergo reductive decomposition in the animal organism at the azo linkage, but the facility with which they are reduced is probably influenced by the presence in the molecule of particular substituent groups. The course of metabolism of dyes containing two or more azo-groups is not known.

8. The work of Hess and Fitzhugh (1953) on the metabolism of some F.D. & C. colours belonging to the triphenylmethane class indicates that in rats these colours were almost completely excreted unchanged in the faeces within 40 hours of oral administration of a 2 per cent. aqueous solution in a dose of 200 mg./rat.

9. Recent investigations on the excretion of some 15 of the food colours manufactured in this country (unpublished communication) indicate that the bulk of the dye administered to rabbits is excreted in the first few hours, but that a significant proportion of the amount injected cannot be accounted for in either the urine or the faeces. An attempt is to be made to identify the breakdown products of these dyes.

10. It appears to have been generally accepted that, so far as general toxicity is concerned, sulphonation has a detoxicating effect, but in view of the known carcinogenic action of certain sulphonated dyes of the disazo and the triphenylmethane classes, this general rule apparently does not hold for carcinogenicity. The water-soluble colours in the German " A " permitted list have been formulated according to the principle of Hecht and Wingler so that each component of the individual dye contains a sulphonic acid group. The report of the German Research Council on Food Colours (1952) refers to the finding of Hecht and Wingler, that water-soluble azo dyes with an aromatic amine as part of the molecule increase significantly the content in the blood of " Heinz bodies " (pigment-like bodies in the erythrocytes, consisting probably of modified haemoglobin). They claim that this morphological modification of the red blood corpuscles is evidence of the formation of toxically active aromatic amines. After the introduction of one or more sulphonic acid groups into each of the amine constituents of the dyes the Heinz tests were negative.

11. The gaps in the published data make it doubtful whether any of the colours under review have been subjected to adequate biological examination. A search of the literature for the past 25 years revealed little material information about acute or chronic toxicity beyond that given in Hesse's survey, though it was evident that increasing attention was being given to the carcinogenicity aspects.

12. The available data do not warrant conclusions to be drawn with confidence about the safety or otherwise of the dyes proposed for use in foods. The reported biological tests in general have been insufficient in design and duration and it is disturbing to find that recent information has cast definite doubt upon some dyes hitherto regarded as satisfactory. Reports have come to hand, for example, that certain F.D. & C. colours—Yellow No. 3, Yellow No. 4, Orange No. 1, Orange No. 2, and Red No. 32—can produce a cathartic action in dogs (Voss et al. 1953). All these colours belong to the azo-class and are either oil-soluble or derived from α- or β-napthol or β-napthylamine. Other investigators have shown that the injection of a solution of F.D. & C. Green No. 2 produces sarcomas in rats (Schiller, 1937; Harris, 1947).

13. It is evident that, if they are to be reliable, pharmacological investigations must include long term tests, which are costly and time-consuming and must have regard to variations in the susceptibility of different animal species before the results of animal experiments can be applied to man. While demonstrable untoward effects in lower animals may rule out the use of a dye in human food, a negative result in animal experiments cannot always be construed as establishing a colour as suitable for use in food.

14. There is need for the formulation of biological tests upon which there can be agreement about minimum requirements for acceptability and about standards for assessment and interpretation of results. Proposals for the investigation of food additives have been propounded by Frazer (1952) which may be summarised as follows:—

(i) *Chemical and physical examination* of the substance.

(ii) *Acute toxicity*—determination of the LD50; oral and parenteral, for mice and rats; check in three other species.

(iii) *Biochemical examination*—effect on gastro-intestinal tract; detailed examination of absorption and metabolism of the substance.

(iv) *Chronic toxicity*—for periods up to the life-span for rats in 50 and 100 times the standard dietary dose; check in three other species; assessment by histopathological, functional, or other tests.

(v) *Tests on human beings*—where possible; in small group trials under direct observation and larger group trials with statistical survey.

Frazer (1953) emphasised the importance of relating pharmacological effects to dosage, and pointed out that with most common drugs the general ratio of ineffective, effective, toxic, and lethal dosage for man is of the order 1 : 10 : 100 : 1,000. He suggested that $\frac{1}{10}$th of the ineffective dose, or $\frac{1}{100}$th of the effective dose (mg./kg. body-weight) might be accepted as a safe dietary level. Frazer's proposals are in general agreement with the views of Lehman et al. (1949).

Carcinogenicity

15. The association of certain chemicals and cancer is well known. Increasing attention has been paid to the high incidence of bladder tumours in persons engaged in the manufacture or handling of aromatic amines, particularly of benzidine, β-naphthylamine and α-naphthylamine.

16. Reports are accumulating of experiments which point to azo compounds and dyestuffs of the triphenylmethane and stilbene series as potent tumour-producing agents in experimental animals. The results obtained make it inevitable that the possible carcinogenic properties of coal-tar dyes when used in foods cannot be ignored.

17. The interpretation of these animal experiments is difficult and complex. For a given dye there must be considered the species of animal used, the method of administration, the dosage employed, and the duration of the test period. The relative susceptibilities of different species of experimental animals and of man are not precisely known and there is the added complication that some substances proven to be carcinogenic in man have so far yielded negative results in animals. Until the contrary can be proved, suspicion must fall on any colour proposed for use in foods which is capable of producing neoplastic reactions in animals.

18. In biological tests for carcinogenicity the following factors are of importance (Hartwell 1951):—

The species, sex and strain of the experimental animal—The rat, rabbit and dog seem to be more resistant to some carcinogens than the mouse, and vice versa. In the monkey none of the powerful carcinogens has been shown to produce tumours.

Dose, site and mode of administration—The dose can be too high as well as too low; the effective dose for one compound may not be the same as that for another closely related one. Some compounds which produce malignancy at the site of injection are inactive when administered by mouth.

Diet—Animals fed a deficient diet may be more susceptible than those fed a diet containing adequate amounts of riboflavin. Biotin has also been reported to have a similar protective action.

Duration of tests—Some compounds tested in mice gave negative results during the first year, but tumours developed during the second year.

19. It would appear that carcinogenicity tests need to be continued for at least 2 years for mice and for perhaps longer for other species; that more than one species of animal should be used; and that the substance should be administered by different routes.

20. Malignant tumours of the liver in rats have been produced by the ingestion of derivatives of p-amino-azobenzene such as o-amino-azotoluene (Yoshida 1932), p-dimethylamino-azobenzene (Butter yellow) (Kinosita 1937) and monomethylamino-azobenzene. The parent substance p-amino-azobenzene has been reported to be inactive in both rats and mice. Comparison of the chemical configuration of these dyes suggests that, for this group, carcinogenicity is related to the presence of one or more methyl groups attached either to the benzene ring or to the side chain. Studies of the carcinogenic potency of a series of substituted aminoazobenzenes, (Suguira 1948; Miller et al. 1949) isomeric aminoazotoluenes, (Crabtree 1949) and azonaphthalenes, (Cook et al. 1940) point to the significance of the position in the molecule of particular groups.

21. Cook et al. (1940; 1942) examined a number of azo-dyes extensively used for colouring food, which showed a structural resemblance to the azo-dyes known to produce liver tumours in mice. The experiments, which were stated to be of adequate duration, led to no tumours which could be attributed to the dyes. The dyes examined were Ponceau 2R (C.I. No. 79), Orange I (C.I. No. 150), Orange II (C.I. No. 151), Amaranth (C.I. No. 184), Naphthalene Orange G (C.I. No. 27) Metanil Yellow (C.I. No. 138), Yellow AB and Yellow OB. The last two oil-soluble dyes, which are included in the U.S. list, were administered by mouth, by subcutaneous

injection and by application to the skin. The others were given in the food, each mouse consuming about 15 to 20 mg. of pure dye weekly. Druchrey, however, found that rats receiving in their diet 2·5 per cent. of Yellow AB and Yellow OB developed cancer of the liver.

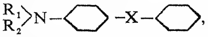
22. Several theories have been formulated to explain the carcinogenic properties of azo-compounds (Cook 1947; Crabtree 1949; Miller et al. 1947; Walpole et al. 1952). Consideration of these and of the experimental evidence on which they are based indicates the need for more information about a variety of factors such as activity in relation to chemical structure, the possible products of metabolic breakdown, the composition of the diet and the possible role of the liver in the transformation of azo-compounds into other substances which themselves may be the true carcinogenic agents.

23. Chemical structure is of course intimately related to metabolic breakdown. The breakdown products which appear to have a particular carcinogenic significance are aromatic amines such as aniline, toluidines, xylidines, naphthylamines, benzidine, tolidine and simple derivatives thereof. Recent work, however, tends to discount aniline as a cause of tumours, and while tumours are not uncommon in workers making toluidines and xylidines there is no reliable evidence that either of these aromatic amines is carcinogenic.

24. Although opinions have been expressed that sulphonated azo-dyes are unlikely to have carcinogenic activity, nevertheless some disazo sulphonated dyes, e.g. Trypan Blue and Evans Blue, have been reported to produce tumours in experimental animals. Some sulphonated triphenylmethane dyes have also been shown to produce tumours when injected into experimental animals (Schiller 1937; Harris 1947); but no tumours resulted from the oral administration of Light Green SF. This difference between subcutaneous injection and oral administration of the triphenylmethane dyes is thought to depend upon the fact that they are poorly absorbed from the gastro-intestinal tract (Hess & Fitzhugh 1953).

25. The literature dealing with the mechanism of carcinogenesis has been reviewed by Boyland (1952), and the following points are of interest:—

β-naphthylamine is said to be the simplest of the carcinogenic aromatic amines; it produces cancer of the bladder in man and in dogs. Because of this specificity of site of action it seems possible that the biological effect may be due to a metabolite excreted in the urine.

Aromatic amines of the type,  , are carcinogenic when:—

(i) R_1 or R_2 is a CH_3 group *and* X is an azo group, or

(ii) X is a stilbene group, or

(iii) X is a single bond.

It will be noted that only in the case of the amino-azo compounds does the presence of at least one methyl group appear to be necessary for carcinogenic activity. In the stilbene and the azo series the introduction of a methyl- or chloro- group into the 4^1 (para) position of the molecule appears to destroy carcinogenic activity.

26. In toxicity studies dosage is usually related to body-weight. There is no evidence, however, that this applies to carcinogenicity, and indeed it is possible that the same dosage of a carcinogen might be as effective in man as in the mouse.

27. Because the results of carcinogenicity tests depend on so many factors even a negative result must be accepted with caution. As in the case of toxicity (para. 14), there is need also for carcinogenicity tests upon which there will be agreement about the most effective methods of administration, the number and species of experimental animals to be employed; and the duration of the tests.

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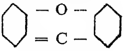
APPENDIX II

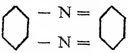
Report of Pharmacology Panel

In September, 1952, the medical members of the Sub-Committee were formed into a panel to examine the pharmacological evidence bearing on the colours under review and to advise on their suitability for use in food.

The Panel reported as follows:—

1. In all we have reviewed 79 colours as shown in the attached list. They include the 19 colours permitted to be used in food in the United States and Canada. The colours belong to one or other of the following chemical classes:—

Chemical Class	*Characteristic Group*	*Number of Colours*
Azo	$-N=N-$	34
Di-, tri-, or poly-azo	two or more $-N=N-$	12
Triphenylmethane	$-C(C_6H_5)_3$	18
Xanthene		6
Pyrazolone		3

Chemical Class	*Characteristic Group*	*Number of Colours*
Azine		3
Nitro	$-NO_2$	1
Diphenylmethane	$=C(C_6H_5)_2$	1
Indigoid	—	1

2. The fact that all these colours have been used extensively in foods and beverages in several countries suggests that the amounts ordinarily consumed cannot be regarded as acutely toxic. The problem before us, therefore, has been to ascertain whether the colours as used are likely to have delayed harmful effects on health.

3. We took note of the following comments of the Departmental Committee on the use of Preservatives and Colouring Matters in Food (1924) on the general relationship between chemical constitution and pharmacological action:

- (*a*) dyes with simple nitro-groups are harmful unless they have been sulphonated;
- (*b*) basic dyes are looked upon with more suspicion than acid dyes;
- (*c*) it is not possible to regard any particular " class " of dyes as safe, since both toxic and non-toxic colours occur in the same class.

An example that sulphonation does not always have a detoxicating effect is the substance Light Green S.F. (C.I. 670) which has been shown to be carcinogenic to experimental animals (Schiller, 1937) although it carries three sulphonic groups.

4. We studied a wide range of literature relating to the biological effects of each colour, including the comprehensive survey by Hesse (1912) of the literature on 106 colours the evidence relating to which he classified as " favourable ", " contradictory " or " unfavourable ". Frequently we found it necessary to depart from Hesse's classification because of experimental evidence which has come to light since his monograph was published.

5. We have found that it is not possible from the structural formula to predict with accuracy the pharmacological action of any colour. The structural formulae of some of the colours are uncertain, and it is not always clear from the literature whether the colours tested were entirely free from impurities.

6. We were struck at the outset by the fact that there is a serious lack of adequate experimental evidence on many dyes, including some used quite extensively. In the absence of conclusive evidence we are unable to recommend any colour unreservedly as safe.

7. Little information is available about the metabolic fate of many colours in the body. Substances soluble in the body fluids which are rapidly eliminated are generally less harmful than substances which, like the fat-soluble dyes, tend to accumulate in one or other organ or tissue. Further, the risk of toxicity is increased where a substance is metabolized to produce one or more breakdown products which are harmful. For example, it is clear from the literature that the N : N linkage is broken down in metabolism, sometimes with the production of substances which have been found to be toxic or carcinogenic, e.g. aniline, toluidine, naphthol, xylidine, naphthylamine, benzidine, and derivatives of them.

8. It is by no means correct or wise to assume that because a substance has no harmful effect on one animal species it would be harmless to other species, including man. For example, doses of belladonna alkaloids, lethal to man and certain other animals, can be tolerated with impunity by rabbits and birds. β-naphthylamine causes cancer of the bladder in the dog and man but not in the rat, rabbit or ferret. Many similar differences in pharmacological action could be given.

9. It is, therefore, clear that to establish the safety or toxicity of a dye sufficient tests on more than one species of animal are essential. The tests should extend over a substantial part of the life-span of the animal, or indeed throughout the whole life and into the next generation. Only by protracted tests can cumulative action and carcinogenic effects be adequately explored.

10. We have found the whole subject of food colours so clouded with uncertainty and lack of definition that, with the safeguarding of the public health as our dominant consideration, we feel that, if colours are to be allowed in food at all, the number permitted should be limited as far as possible. Such a list should exclude—for the present, at any rate—all dyes reported to cause toxic effects or tumour formation in any animal, or which seem likely to be broken down in the body into substances producing such effects.

11. We recommend that 35 of the dyes which we have reviewed should be rejected because examination of the experimental evidence shows that they have definitely harmful effects on health, or that their chemical structure includes groupings likely to be set free in the body which have been shown to cause cancer or other harmful effects in animals or man. These 35 dyes have been considered unsuitable for use in food and are labelled " C " in the list.

12. We have labelled " A " 12 dyes which have not so far been shown to produce any harmful effects and which, from their structure and physicochemical properties seem unlikely to be harmful in the amounts ordinarily consumed.

13. The remaining 32 dyes have been put into an intermediate (" B ") category. This consists of those food colours about which there was no direct evidence of toxicity or harmfulness, but about which the evidence was inadequate or uncertain owing to the fact that the degree of purity of the dye was not specified, or because of some doubt about the significance of the experimental findings.

14. We, therefore, define the three categories of colours as follows:—

A. Colours, which, from the available evidence, would seem unlikely to be harmful when consumed in foods in the customary amounts.

B. Colours for which the available evidence is deficient or conflicting although there is no apparent reason on structural or other grounds to expect them to be harmful in the amounts ordinarily consumed.

C. Colours which have been shown, or are suspected, to have harmful effects on health.

15. If the Sub-Committee decide to draw up a permitted list of colours the Panel—

(*a*) recommend that it should be provisional only; as knowledge advances colours of proved harmlessness might be added to the list and any colours subsequently found to be harmful removed from the list;

(*b*) recommend that preference should be given to colours in category A;

(*c*) would raise no objection to the inclusion in the permitted list of colours in the B category, provided it is understood that their inclusion is on a less secure basis than for colours in category A;

(*d*) advise the exclusion from the permitted list of all colours in category C unless subsequent investigations justify re-classification in category A.

16. The Panel suggest that a stated period of, say 3–5 years, should be allowed to enable full tests to be made of all colours included in the provisional list, and that then a further review of the position should be made to see if a list could be drawn up on a more satisfactory basis. The Panel express no views as to the agency which should undertake the testing.

17. Each colour in the permitted list should be defined by its chemical formula and a specification of purity should be prescribed.

18. The Panel wish to acknowledge their indebtedness to Professors Bergel, Boyland and Cook for advice on carcinogenicity.

List of Submitted Colours and Panel Classifications

Sub-Committee Ref. Number	Colour	C.I. (1924) No.	Common Name of Colour	Chemical Class	On list submitted by:—*				Panel Classification	Remarks
					A.B.C.M.	B.B.I.R.A.	B.E. & F.C.M.	C.C. & C.A.		
1	RED	79	Ponceau MX	Azo	+	+	+	+	B	
2		185	Ponceau 4R	,,	+	+	+	+	A	
3		179	Carmoisine	,,	+	+	+	+	A	
4		184	Amaranth	,,	+	+	+	+	A	F.D. & C. Red No. 2
5		30	Red 1 OB	,,	+	+	+	+	B	
6		773	Erythrosine BS	Xanthene	+	+	+	+	B	F.D. & C. Red No. 3
7		749	Rhodamine B	,,	+	+	+	+	B	
8		31	Red 2 G	Azo	+	+	+	+	B	
9		57	Red 6B	,,	+	+	+	+	A	
10		225	Red FB	,,	+	+	+	+	A	
11		—	Ponceau SX	,,	+	+	+	+	A	F.D. & C. Red No. 4
12		80	Ponceau 3R	,,	.	.	+	+	B	F.D. & C. Red No. 1
13		89	Ponceau Cryst. 6R	,,	.	.	+	+	C	
14		692	Acid Magenta II	Triphenylmethane	.	.	+	+	A	
15		752	Rhodamine 6G	Xanthene	.	.	+	+	B	
16		750	Rhodamine G	,,	.	.	+	+	B	
17		252	Brilliant Croceine	Disazo	.	.	+	+	C	
18		258	Sudan IV	,,	.	.	+	+	C	
19		771	Eosine Scarlet	Xanthene	.	.	+	.	B	
20		777	Rose Bengal	,,	.	.	+	.	B	
21		280	Croceine Scarlet 5R	Disazo	.	.	+	.	C	
22		85	Benzyl Bordeau B	Azo	.	.	.	+	C	
23		88	Acid Bordeau B	,,	.	.	.	+	C	
24		774	Phloxine	Xanthene	.	.	.	+	B	
25		113	Sudan Red G	Azo	.	+	.	.	C	
26		82	Oil Red 2R	,,	.	.	.	+	C	

27	ORANGE	150	ORANGE I	Azo	+	+	+	+	C	F.D. & C. Orange No. 1
28		27	ORANGE G	„	+	+	+	+	B	
29		26	ORANGE RN	„	+	+	+	+	B	
30		—	OIL ORANGE TX	„	+	+	+	.	C	F.D. & C. Orange No. 2.
31		73	OIL ORANGE XX	„	+	+	+	.	C	Similar to F.D. & C. Red No. 32
32		20 or 21	CHRYSOIDINE	„	.	.	+	+	C	
33		151	ORANGE II	„	.	.	.	+	C	
34	YELLOW	640	TARTRAZINE	Pyrazolone	+	+	+	+	A	F.D. & C. Yellow No. 5
35		10	NAPTHOL YELLOW S (Na & K salt)	Nitro	+	+	+	+	A	F.D. & C. Yellows No. 1 and 2
36		639	YELLOW 2G	Pyrazolone	+	+	+	+	B	
37		—	YELLOW RFS	Azo	+	+	+	+	B	
38		—	YELLOW RY	„	+	+	+	+	B	
39		—	SUNSET YELLOW FCF	„	+	+	+	+	A	F.D. & C. Yellow No. 6
40		—	OIL YELLOW HA	„	+	+	+	.	C	
41		—	OIL YELLOW SEG	Pyrazolone	+	+	+	.	B	
42		16	ACID YELLOW G	Azo	.	.	+	.	B	
43		18	FAST YELLOW R	„	.	.	+	+	B	
44		655	AURAMINE	Diphenylmethane	.	.	+	+	B	
45		22	OIL YELLOW AB	Azo	.	.	+	+	C	F.D. & C. Yellow No. 3
46		61	OIL YELLOW OB	„	.	.	+	+	C	F.D. & C. Yellow No. 4
47		23	OIL YELLOW GG	„	.	.	+	.	B	
48		138	METANIL YELLOW	„	.	.	.	+	C	
49	GREEN	670	LIGHT GREEN SF	Triphenylmethane	+	+	+	+	C	F.D. & C. Green No. 2
50		737	GREEN S	„	+	+	+	+	B	
51		666	GUINEA GREEN B	„	.	+	+	+	C	F.D. & C. Green No. 1
52		—	FAST GREEN FCF	„	.	+	+	+	C	F.D. & C. Green No. 3
53		662	BRILLIANT GREEN CRYST. Y	„	.	.	+	.	B	
54		657	MALACHITE GREEN	„	.	.	.	+	C	
55	BLUE	671	BRILLIANT BLUE FCF (NH_4 salt)	Triphenylmethane	+	+	.	+	C	
56		—	„ „ „ (Na salt)	„	+	+	+	+	C	F.D. & C. Blue No. 1
57		672	BLUE VRS	„	+	+	+	+	A	
58		1,180	INDIGO CARMINE	Indigoid	+	+	+	+	A	F.D. & C. Blue No. 2

List of Submitted Colours and Panel Classifications—*continued*

Sub-Committee Ref. Number	Colour	C.I. (1924) No.	Common Name of Colour	Chemical Class	On list submitted by:—* A.B.C.M.	B.B.I.R.A.	B.E. & F.C.M.	C.C. & C.A.	Panel Classification	Remarks
59	BLUE	518	Chlorazol Sky Blue FF	Disazo	.	.	+	.	C	
60		406	Direct Blue 2B	,,	.	.	+	.	C	
61		707	Water Blue	Triphenylemethane	.	.	+	+	C	
62		861	Induline	Azine	.	.	+	+	C	
63		860	,, (spirit soluble)	,,	.	.	+	+	C	
64		289	Coomassie Navy Blue	Disazo	.	.	+	.	C	
65		661	Turquoise Blue G	Triphenylmethane	.	.	+	.	B	
66		714	Patent Blue A	,,	.	.	.	+	B	
67		704	Alkali Blue	,,	.	.	.	+	C	
68	VIOLET	698	Violet 5BN	Triphenylmethane	+	+	+	+	B	
69		697	Acid Violet 6B	,,	.	+	+	.	B	F.D. & C. Violet No. 1
70		680	Methyl Violet	,,	.	.	+	+	C	
71		695	Acid Violet 4BN	,,	.	.	.	+	B	
72	BROWN	—	Brown FK	Azo	+	+	+	+	B	
73		—	Chocolate Brown	Disazo	+	+	+	+	B	
74		—	Baking Brown AW	Polyazo	+	+	+	+	B	
75		612	Baking Brown	,,	.	.	.	+	C	
76		331 or 332	Bismark Brown	Disazo	.	.	+	+	C	
77		234	Light Brown	,,	.	.	.	+	C	
78	BLACK	—	Crispin Black G	Triazo	+	+	.	.	B	Subsequently withdrawn
79		865	Nigrosine	Azine	.	.	+	+	C	

* A.B.C.M.—Association of British Chemical Manufacturers.
B.B.I.R.A.—British Baking Industries Research Association.
B.E. & F.C.M.—British Essence Manufacturers' Association and Flavouring Compound Manufacturers' Association.
C.C. & C.A.—Cocoa, Chocolate and Confectionery Alliance Ltd.

APPENDIX III

List of Permitted Colours

(i) Colours of natural origin

Appropriate Designation	Description
Alkannet	The colouring matter obtained from the roots of *Alkanna tinctoria*.
Annatto	The colouring matter obtained from the seed pods of *Bixa orellana*.
Caramel	The colouring matter obtained by heating sugar.
Carotene	The carotenoid colouring matters obtained from leaves and vegetables.
Chlorophyll	The green colouring matter obtained from the leaves, etc., of plants.
Cochineal	The colouring matter obtained from the female insect *Coccus cacti*.
Flavine	The colouring matter obtained from quercitron bark.
Orchil	The colouring matter obtained from lichens of the species *Roccella*.
Persian berry	The colouring matter obtained from the berries of the Buckthorn (*Rhamnus*) family.
Saffron	The colouring matter obtained from the styles and stigmas of *Crocus sativus*.
Turmeric	The colouring matter obtained from the rhizomes of *Curcuma longa*.
Bole or Iron oxide	Armenian bole or prepared ferric oxide.
Carbon black	Pure finely divided carbon.

(ii) Synthetic Colours

Sub-Committee Ref: No:	Appropriate Designation	Scientific Name	Colour Index (1924) Number
1.	Red No. 1	di-sodium salt of *m*-xylene-azo-β-naphthol-1-3 : 6-disulphonic acid.	79
2.	Red No. 2	tri-sodium salt of 4-sulpho-α-naphthalene-azo-β-naphthol-6 : 8-disulphonic acid.	185
3.	Red No. 3	di-sodium salt of 4-sulpho-α-naphthalene-azo-1-naphthol-4-sulphonic acid.	179
4.	Red No. 4	tri-sodium salt of 4-sulpho-α-naphthalene-azo-β-naphthol-3 : 6-disulphonic acid.	184
5.	Red No. 5	di-sodium salt of benzene-azo-8-amino-1-naphthol-3 : 6-disulphonic acid.	30
6.	Red No. 6	sodium (or potassium) salt of tetra-iodo-fluorescein.	773
7.	Red No. 7	hydrochloride of diethyl-*m*-amino-phenol-phthalein.	749
8.	Red No. 8	di-sodium salt of benzene-azo-8-acetylamino-1-naphthol-3 : 6-disulphonic acid.	31

(ii) Synthetic Colours—(*continued*)

Sub-Committee Ref. No.	Appropoiate Designation	Scientific Name	Colour Index (1924) Number
9.	Red No. 9 ...	di-sodium salt of *p*-acetylaminobenzene-azo-8-acetylamino-1-naphthol-3 : 6-disulphonic acid.	57
10.	Red No. 10	di-sodium salt of sulphobenzenylaminothiocresol-azo-1-naphthol-4-sulphonic acid.	225
11.	Red No. 11	di-sodium salt of 2(-5-sulpho-2 : 4-xylylazo)-1-naphthol-4-sulphonic acid.	—
12.	Red No. 12	di-sodium salt of 1-pseudocumylazo-2-naphthol-3 : 6-disulphonic acid.	80
15.	Red No. 13	ethyl-ester of diethyldiamino-*o*-carboxyphenyl-xanthenyl chloride.	752
28.	Orange No. 14	di-sodium salt of benzene-azo-2-naphthol-6 : 8-disulphonic acid.	27
29.	Orange No. 15	sodium salt of benzene-azo-2-naphthol-6-sulphonic acid.	26
47.	Yellow No. 16	benzene-azo-resorcinol	23
34.	Yellow No. 17	tri-sodium salt of 4-*p*-sulphobenzene-azo-1-*p*-sulphophenyl-5-hydroxy-pyrazol-3-carboxylic acid.	640
35.	Yellow No. 18	di-sodium (or potassium) salt of 2 : 4-dinitro-1-naphthol-7-sulphonic acid.	10
36.	Yellow No. 19	di-sodium salt of 4-*p*-sulphobenzene-azo-1-*o*-*m*-dichloro-*p*-sulphophenyl-3-methyl-5-hydroxy-pyrazol.	639
37.	Yellow No. 20	di-sodium salt of *p*-sulphophenyl-azo-sulphomethyl-amino-benzene.	—
38.	Yellow No. 21	di-sodium salt of *p*-sulphobenzene-azo-resorcinol-sulphonic acid.	—
39.	Yellow No. 22	di-sodium salt of 1-*p*-sulphophenyl-azo-2-naphthol-6-sulphonic acid.	—
41.	Yellow No. 23	4-*m*-xylylazo-1-phenyl-3-methyl-5-pyrazolone.	—
50.	Green No. 24	sodium salt of tetramethyldiamino-diphenyl-β-hydroxynaphthyl-carbinol disulphonic acid anhydride.	737
57.	Blue No. 25	sodium salt of tetraethyldiamino-triphenylcarbinol disulphonic acid anhydride.	672
58.	Blue No. 26	di-sodium salt of indigotin-5 : 5-disulphonic acid.	1180
68.	Violet No. 27	sodium salt of dibenzyltetraethyltriaminotriphenylcarbinol disulphonic acid anhydride.	698
69.	Violet No. 28	sodium salt of dibenzyldiethyldimethyltriamino-triphenyl-carbinol disulphonic acid anhydride.	697
72.	Brown No. 29	A mixture consisting *essentially* of:— The di-sodium salt of 4 : 6-di-(*p*-sulphophenylazo)-1 : 3-diamino-benzene; and The mono-sodium salt of 5-(*p*-sulphophenyl azo)-2 : 4-diamino-toluene.	—

(ii) Synthetic colours—(*continued*)

Sub-Committee Ref. No.	Appropriate Designation	Scientific Name	Colour Index (1924) Number
73.	Brown No. 30	The product of coupling diazotised naphthionic acid (1-naphthylamine-4-sulphonic acid) with a mixture of morin (C.I. No. 1232) and maclurin (pentahydroxy-benzophenone).	—
	Brown No. 31	The di-sodium salt of bis-4-sulpho-1-naphthalene - disazo - 2 : 4 - dihydroxy - benzyl alcohol.	
74.	Brown No. 32	tetra-sodium salt of diphenyl-disazo-bis-(- *m* - phenylenediamine - disazo - bis - *p* - sulpho-benzene).	

NOTES:

1. The inclusion of Brown No. 29, No. 30 and No. 31 (Ref. Nos. 72 and 73) is subject to verification that these colours can be produced of constant composition.

2. The aluminium or calcium salts (lakes) of any of the listed water-soluble colours may be used for the external colouring of foods.

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